

Bill No. SB 2496

Barcode 631862 Comm: RCS 04/10/2007 10:17 PM

587-2299-07

Proposed Committee Substitute by the Committee on Health
Policy

1 A bill to be entitled

2 An act relating to stem cell research; creating

3 s. 381.99, F.S.; providing a short title;

4 providing definitions; creating the Stem Cell

5 Research Advisory Council and Biomedical Ethics

6 Advisory Council within the Department of

7 Health; providing for membership and terms;

8 providing duties and responsibilities;

9 requiring the Secretary of Health to make

10 grants-in-aid from the Biomedical Research

11 Trust Fund for stem cell research; providing

12 requirements relating to applications for and

13 awards of such grants-in-aid; providing

14 specifications for moneys to be made available

15 from the trust fund for stem cell research

16 grants-in-aid; providing restrictions and

17 requirements for uses of funds from such

18 grants-in-aid; providing an appropriation;

19 amending s. 20.435, F.S.; revising references;

20 amending s. 381.86, F.S.; providing an

21 exception to the Institutional Review Board for

22 the Stem Cell Research Advisory Council and

23 Biomedical Ethics Advisory Council; requiring

24 the Department of Health to prepare and

25 distribute a publication regarding the process,

26 options, medical uses, risks, and benefits of

27 umbilical cord blood collection; providing an

28 effective date.

29

30 Be It Enacted by the Legislature of the State of Florida:

31

Bill No. SB 2496

Barcode 631862

587-2299-07

1 Section 1. Section 381.99, Florida Statutes, is
2 created to read:

3 381.99 Florida Hope Offered through Principled,
4 Ethically Sound Stem Cell Research Act.--

5 (1) SHORT TITLE.--This section may be cited as the
6 "Florida Hope Offered through Principled, Ethically Sound Stem
7 Cell Research Act."

8 (2) DEFINITIONS.--As used in this section, the term:

9 (a) "Adult stem cell" means a cell found within
10 differentiated tissue or an organ which can renew itself and
11 give rise to the major cell types of the tissue or organ. This
12 includes cells from the fetal to adult stages of development.

13 (b) "Amniotic stem cell" means a cell extracted from
14 human amniotic fluid or a placenta.

15 (c) "Embryonic stem cell" means a cell obtained from
16 the undifferentiated inner mass of an early stage embryo.

17 (d) "Stem cell" means a cell that retains the
18 potential to generate some or all other cell types.

19 (3) STEM CELL RESEARCH ADVISORY COUNCIL.--There is
20 created the Stem Cell Research Advisory Council within the
21 Department of Health.

22 (a)1. The advisory council shall consist of the
23 Secretary of Health or his or her designee, who shall act as
24 chair, and six additional members, who shall be appointed as
25 follows:

26 a. Two persons appointed by the Governor, one of whom
27 shall be an academic researcher in the field of stem cell
28 research and one of whom shall have a background in bioethics.

29 b. One person appointed by the President of the
30 Senate, who shall have a background in private-sector stem
31 cell funding and development or public-sector biomedical

Bill No. SB 2496

Barcode 631862

587-2299-07

1 research and funding.

2 c. One person appointed by the Speaker of the House of
3 Representatives, who shall have a background in private-sector
4 stem cell funding and development or public-sector biomedical
5 research and funding.

6 d. One person appointed by the President of the
7 Senate, who shall have a background and experience in
8 public-sector or private-sector stem cell research and
9 development.

10 e. One person appointed by the Speaker of the House of
11 Representatives, who shall be an executive of a biotech
12 company, or his or her designee.

13 2. Each member shall be appointed to a term of 2 years
14 commencing on October 1, 2007. A member may not serve for more
15 than two consecutive 2-year terms; however, for the purpose of
16 providing staggered terms, of the initial appointments, three
17 members shall be appointed to 1-year terms and three members
18 shall be appointed to 2-year terms. Any vacancy on the
19 advisory council shall be filled in the same manner as the
20 original appointment. All initial appointments shall be made
21 by October 1, 2007. The first meeting shall take place no
22 later than November 1, 2007. All meetings are subject to the
23 call of the chair. Members shall meet at least twice a year or
24 as often as necessary to discharge their duties but may not
25 hold more than four meetings during any 12-month period.
26 Members shall serve without compensation but are entitled to
27 reimbursement for per diem and travel expenses in accordance
28 with s. 112.061.

29 (b) The advisory council shall:

30 1. Develop a donated funds program for recommendation
31 to the Secretary of Health to encourage the development of

Bill No. SB 2496

Barcode 631862

587-2299-07

1 funds other than state appropriations for human adult stem
2 cell research in the state.

3 2. Examine and identify specific ways to improve and
4 promote for-profit and not-for-profit human adult stem cell
5 and related research in the state, including, but not limited
6 to, identifying sources of public and private funding for such
7 research, maintaining existing human adult stem cell-related
8 businesses, recruiting new human adult stem cell-related
9 businesses to the state, and recruiting scientists and
10 researchers in such fields to the state and state
11 universities.

12 3. Develop a biomedical research grant program for
13 recommendation to the Secretary of Health which shall provide
14 grants-in-aid to eligible state institutions for the
15 advancement of human adult stem cell research.

16 4. Develop, no later than December 1, 2007, an
17 application for grants-in-aid under this section for
18 recommendation to the Secretary of Health for the purpose of
19 conducting human adult stem cell research.

20 5. Review applications from eligible institutions for
21 grants-in-aid on and after December 1, 2007, and provide to
22 the Secretary of Health recommendations for grant awards.

23 6. Review the stem cell research conducted by eligible
24 institutions that receive such grants-in-aid.

25 (c) The advisory council shall submit an annual
26 progress report on the status of biomedical research in the
27 state to the Florida Center for Universal Research to
28 Eradicate Disease and to the Governor, the Secretary of
29 Health, the President of the Senate, and the Speaker of the
30 House of Representatives by June 30. The report must include:

31 1. The amount of grants-in-aid awarded to eligible

Bill No. SB 2496

Barcode 631862

587-2299-07

1 institutions from the Biomedical Research Trust Fund.

2 2. The names of the recipients of such grants-in-aid.

3 3. The current status and progress of stem cell
4 research in the state.

5 4. A list of research projects supported by
6 grants-in-aid awarded under the program.

7 5. A list of publications in peer-reviewed journals
8 involving research supported by grants-in-aid awarded under
9 the program.

10 6. The total amount of biomedical research funding
11 currently flowing into the state.

12 7. New grants for biomedical research which were
13 funded based on research supported by grants-in-aid awarded
14 under the program.

15 8. All other materials that the advisory council
16 considers advisable to include.

17 (d) Advisory council members shall disclose any
18 conflict of interest or potential conflict of interest to the
19 Secretary of Health.

20 (e) The Department of Health shall provide
21 administrative staff to assist the advisory council in
22 developing the application for the grants-in-aid, reviewing
23 the applications, preparing the written consent form described
24 in paragraph (6)(b), and performing other administrative
25 functions as the advisory council requires.

26 (4) BIOMEDICAL ETHICS ADVISORY COUNCIL.--There is
27 created within the Department of Health the Biomedical Ethics
28 Advisory Council.

29 (a)1. The advisory council shall consist of the
30 Secretary of Health or his or her designee, who shall act as
31 chair, and six additional members, who shall be appointed as

Bill No. SB 2496

Barcode 631862

587-2299-07

1 follows:

2 a. Two persons appointed by the Governor.

3 b. One person appointed by the President of the
4 Senate.

5 c. One person appointed by the Speaker of the House of
6 Representatives.

7 d. One person appointed by the Minority Leader of the
8 Senate.

9 e. One person appointed by the Minority Leader of the
10 House of Representatives.

11 2. All members must demonstrate knowledge and
12 understanding of the ethical, medical, and scientific
13 implications of stem cell research and should also demonstrate
14 knowledge of related fields, including, but not limited to,
15 genetics, cellular biology, and embryology. Each member shall
16 be appointed to a term of 4 years commencing on October 1,
17 2007; however, for the purpose of providing staggered terms,
18 of the initial appointments, three members shall be appointed
19 to 2-year terms and three members shall be appointed to 4-year
20 terms. A member may not serve for more than two consecutive
21 terms. Any vacancy on the advisory council shall be filled in
22 the same manner as the original appointment. All initial
23 appointments shall be made by October 1, 2007. The first
24 meeting shall take place no later than November 1, 2007. All
25 meetings are subject to the call of the chair. Members shall
26 meet at least twice a year or as often as necessary to
27 discharge their duties but may not hold more than one meeting
28 per month during any 12-month period. Members shall serve
29 without compensation but are entitled to reimbursement for per
30 diem and travel expenses in accordance with s. 112.061.

31 (b) The advisory council shall review all stem cell

Bill No. SB 2496

Barcode 631862

587-2299-07

1 research that is funded or supported in any manner through the
2 Biomedical Research Trust Fund to ensure the adherence to
3 ethical and safety guidelines and procedures as set forth by
4 federal ethical standards established by the United States
5 Department of Health and Human Services.

6 (5) BIOMEDICAL RESEARCH TRUST FUND AND
7 GRANTS-IN-AID.--

8 (a) The Secretary of Health shall make grants-in-aid
9 from the Biomedical Research Trust Fund in accordance with the
10 provisions of this section.

11 (b) The Department of Health shall require any
12 applicant for a grant-in-aid under this section, for the
13 purpose of conducting stem cell research, to submit a complete
14 description of the applicant's organization, the applicant's
15 plans for stem cell research, the applicant's proposed funding
16 for such research from sources other than the state, and the
17 applicant's proposed arrangements concerning financial
18 benefits to the state as a result of any patent, royalty
19 payment, or similar right resulting from any stem cell
20 research made possible by the awarding of the grant-in-aid.

21 The Stem Cell Research Advisory Council shall provide
22 recommendations to the Secretary of Health with respect to
23 awarding such grants-in-aid after considering the
24 recommendations of the Biomedical Ethics Advisory Council.

25 (c) Beginning with the 2007-2008 fiscal year, and for
26 10 consecutive years thereafter, not less than \$20 million
27 shall be made available annually from the Biomedical Research
28 Trust Fund within the Department of Health for grants-in-aid
29 to eligible institutions for the purpose of conducting adult
30 stem cell research pursuant to this section. Up to 15 percent
31 of the funds may be used for administrative costs. Any

Bill No. SB 2496

Barcode 631862

587-2299-07

1 unexpended funds not used for grants-in-aid during the current
2 fiscal year shall be carried forward for the following fiscal
3 year to fund the grants-in-aid.

4 (6) USE OF FUNDS; REQUIREMENTS AND RESTRICTIONS.--

5 (a) Funds provided under this section may be used only
6 for research involving:

7 1. Human adult stem cells, including, but not limited
8 to, adult stem cells derived from umbilical cord blood and
9 bone marrow. Funding for research may be given for human adult
10 stem cells derived from postmortem tissues, other than from
11 medically induced abortions. Funds may be used for studies of
12 human adult stem cells obtained from normal or transformed
13 tissues.

14 2. Amniotic stem cells extracted from human amniotic
15 fluid or placentas which are otherwise discarded after birth.

16 (b) Amniotic and adult stem cell material may be
17 donated only for research purposes with the informed consent
18 of the donor.

19 (c) Funds may not be used for research using human
20 embryonic stem cells that are derived by a process entailing
21 the donor embryo's death or destruction.

22 (7) CONTINUING APPROPRIATION.--Beginning in the
23 2007-2008 fiscal year, the sum of \$20 million is appropriated
24 annually from recurring funds in the General Revenue Fund to
25 the Biomedical Research Trust Fund within the Department of
26 Health for the purpose of carrying out the provisions of this
27 section. The amount of funds appropriated may not exceed \$200
28 million for the 10-year period beginning in the 2007-2008
29 fiscal year and ending in the 2016-2017 fiscal year.

30 Section 2. Paragraph (h) of subsection (1) of section
31 20.435, Florida Statutes, is amended to read:

Bill No. SB 2496

Barcode 631862

587-2299-07

1 20.435 Department of Health; trust funds.--

2 (1) The following trust funds are hereby created, to
3 be administered by the Department of Health:

4 (h) Biomedical Research Trust Fund.

5 1. Funds to be credited to the trust fund shall
6 consist of funds deposited pursuant to ss. ~~s.~~ 215.5601,
7 288.955, and 381.99 and any other funds appropriated by the
8 Legislature. Funds shall be used for the purposes of the James
9 and Esther King Biomedical Research Program, ~~and~~ the William
10 G. "Bill" Bankhead, Jr., and David Coley Cancer Research
11 Program, and the Florida Hope Offered through Principled,
12 Ethically Sound Stem Cell Research Act as specified in ss.
13 215.5602, 288.955, ~~and~~ 381.922, and 381.99. The trust fund is
14 exempt from the service charges imposed by s. 215.20.

15 2. Notwithstanding the provisions of s. 216.301 and
16 pursuant to s. 216.351, any balance in the trust fund at the
17 end of any fiscal year shall remain in the trust fund at the
18 end of the year and shall be available for carrying out the
19 purposes of the trust fund. The department may invest these
20 funds independently through the Chief Financial Officer or may
21 negotiate a trust agreement with the State Board of
22 Administration for the investment management of any balance in
23 the trust fund.

24 3. Notwithstanding s. 216.301 and pursuant to s.
25 216.351, any balance of any appropriation from the Biomedical
26 Research Trust Fund which is not disbursed but which is
27 obligated pursuant to contract or committed to be expended may
28 be carried forward for up to 3 years following the effective
29 date of the original appropriation.

30 4. The trust fund shall, unless terminated sooner, be
31 terminated on July 1, 2008.

Bill No. SB 2496

Barcode 631862

587-2299-07

1 Section 3. Subsection (1) of section 381.86, Florida
2 Statutes, is amended to read:

3 381.86 Institutional Review Board.--

4 (1) The Institutional Review Board is created within
5 the Department of Health in order to satisfy federal
6 requirements under 45 C.F.R. part 46 and 21 C.F.R. parts 50
7 and 56 that an institutional review board review all
8 biomedical and behavioral research on human subjects which is
9 funded or supported in any manner by the department, except
10 that a separate Stem Cell Research Advisory Council and
11 Biomedical Ethics Advisory Council shall be appointed under s.
12 381.99.

13 Section 4. (1) The Department of Health shall prepare
14 an educational publication that includes objective information
15 regarding:

16 (a) The medical processes involved in the collection
17 of umbilical cord blood;

18 (b) The medical risks to the mother and her newborn
19 child of umbilical cord blood collection;

20 (c) The options available to a mother relating to stem
21 cells that are contained in the umbilical cord blood after the
22 delivery of her newborn, including:

23 1. Discarding the stem cells;

24 2. Donating the stem cells to a public umbilical cord
25 blood bank;

26 3. Storing the stem cells in a family or private
27 umbilical cord blood bank for use by family members; or

28 4. Storing the stem cells for family use through a
29 family or sibling donor banking program that provides free
30 collection, processing, and storage where there is a medical
31 need;

Bill No. SB 2496

Barcode 631862

587-2299-07

1 (d) The current and potential future medical uses,
2 risks, and benefits of umbilical cord blood collection to a
3 mother, her newborn child, and her biological family;

4 (e) The current and potential future medical uses,
5 risks, and benefits of umbilical cord blood collection to
6 persons who are not biologically related to a mother or her
7 newborn child;

8 (f) Any costs that may be incurred by a pregnant woman
9 who chooses to make an umbilical cord blood donation;

10 (g) Options for ownership and future use of the
11 donated material; and

12 (h) The average cost of public and private umbilical
13 cord blood banking.

14 (2) The department shall update the publication as
15 necessary.

16 (3) The department shall distribute the pamphlet free
17 of charge to physicians and health care institutions upon
18 request and shall make the pamphlet available on its website
19 in printable format.

20 (4) The department shall encourage health and maternal
21 care professionals providing health care services to a
22 pregnant woman, when those health care services are directly
23 related to her pregnancy, to provide the pregnant woman with
24 the publication by the end of her second trimester.

25 Section 5. This act shall take effect July 1, 2007.